UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	**Criminal No.: 09-CR-10330-GAO**
v.	)	
(1) STRYKER BIOTECH, LLC,	)	
(2) MARK PHILIP,	)	
(3) WILLIAM HEPPNER,	)	
(4) DAVID ARD and	)	
(5) JEFFREY WHITAKER,	)	
Defendants	)	

UNITED STATES' TRIAL BRIEF

The United States respectfully submits this trial brief in the above-captioned matter.

I. Charges in the Superseding Indictment

The Superseding Indictment charges Stryker Biotech, LLC ("Stryker"), Mark Philip (President), William Heppner (VP Sales), David Ard (Regional Sales Manager), and Jeffrey Whitaker (Regional Sales Manager) with offenses related to their illegal promotion of OP-1, Calstrux, and the combination of the two devices between February 2006 and February 2008.

A. Conspiracy to Defraud the FDA (First Prong of Count 1)

Count I of the Superseding Indictment charges the defendants with conspiracy to (a) defraud the United States Food and Drug Administration ("FDA"), and (b) to commit wire fraud. The first object of the conspiracy was to willfully impede by trickery and deceit the FDA's lawful function of protecting the health and safety of the American public by regulating the safety and efficacy of medical devices. The conspirators evaded the FDA's lawful regulatory authority to approve or reject medical devices prior to their introduction to the market through the deliberate manipulation of

physicians into using a mixture of Calstrux and OP-1 Putty that was never approved by the FDA.[1] They also evaded the FDA's lawful authority to evaluate and decide the manner in which a medical device should be used by deliberately manipulating physicians into using a mixture of one unit of OP-1 Putty and Calstrux that was contrary to the FDA approved labels for each product.[2] Despite a growing association between adverse events and the use of the combination of OP-1 and Calstrux, and in the face of explicit training that promotion of the unapproved combination was illegal, the conspirators continued to illegally promote and cause the promotion of the combination of OP-1 and Calstrux through false and misleading statements to, and concealment of material facts from, physicians, IRBs, and the FDA. The effect of the illegal promotion of the unapproved combination was to conduct clinical testing on an unsuspecting public, without the required oversight of the FDA,[3] all designed to thwart the FDA's lawful function to regulate medical devices for the protection of the American public. The goal of the conspiracy was to obtain millions of dollars in additional sales from OP-1 to which Stryker was not entitled under the limited Humanitarian Device Exemptions that had been granted by the FDA.

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[1]Under the FDCA, all Class III devices were required to obtain premarket approval ("PMA") before the device could be introduced into interstate commerce, or the device was adulterated. *See*, 21 U.S.C. §§ 331(a), 351(f)(1), 360(e). Although not here separately substantively charged, promotion of the combination of OP-1 and Calstrux was illegal because Stryker never obtained FDA approval for the mixture.

[2]Promotion of one unit of OP-1 Putty with Calstrux was inconsistent with the FDA approved label for OP-1 Putty which called for two units of OP-1 Putty to be mixed with a small amount of CMC (not Calstrux), and contrary to the label for Calstrux, which by August 2006 contained an express precaution that Calstrux should not be mixed with other products.

[3]Under the FDCA, an exemption could be obtained from the FDA for clinical investigation of devices to determine the safety and effectiveness of the device. 21 U.S.C. § 360j(g) and 21 C.F.R. Part 812. Submission, and subsequent approval, of an investigational device exemption ("IDE") permitted a device that was otherwise required to obtain a PMA to be shipped lawfully in interstate commerce for the purpose of conducting clinical investigations. Superseding Indictment, ¶ 5.C.

These defendants used various deceitful and dishonest means to accomplish their conspiracy to impede the FDA's lawful authority to regulate the safety and efficacy of medical devices. One of those methods was to train the sales force to illegally promote Calstrux as an "extender" or "carrier" for OP-1, and to encourage them to make such sales of the unapproved mixture through quotas, bonuses, reviews, and feedback. Another method was to train the sales force to respond to price concerns expressed by surgeons and hospital staff that two units of OP-1 Putty per spinal surgery (over $10,000) was around twice as expensive as a competitive bone morphogenic protein by telling surgeons and hospital staff that one unit of OP-1 and Stryker's "extender" or "carrier" (Calstrux) was competitive on price and efficacy. The Stryker sales force provided widely varying and untested recipes for mixing Calstrux and OP-1 were provided to surgeons and surgical staff for use in surgeries.

To induce surgeons to use the unapproved combined product, various false statements and material omissions were used regarding the nature of the devices (*e.g.* the mixture was all OP-1), the meaning of FDA approvals (*e.g.* regarding HDEs and off-label use), the testing of the mixture (or lack thereof), the adverse events from use of the mixture, and the information on the FDA approved labels (OP-1 Putty approved at two units, not one unit; omitting warning not to mix Calstrux with any other product). To induce IRBs to approve the use of OP-1 and not withdraw the approvals, various false statements and material omissions were used and caused to be used including not informing IRBs of adverse events from the use of the mixture; not informing IRBs about the inappropriate off-label uses of OP-1 or uses inconsistent with the IRB's approval, including in a mixture with Calstrux; not informing the IRBs that the mixture of OP-1 and Calstrux was contrary to the warning in the Calstrux label not to mix Calstrux with any product; all while

simultaneously providing discounted pricing proposals to hospital purchasing staff to purchase the two products for use together.

Stryker also engaged in trickery, fraud, and deceit directed at the FDA to lull the agency into inaction regarding OP-1. In June 2006, the FDA noted an unusual number of serious adverse events associated with the use of a mixture of Calstrux and OP-1 during surgeries (adverse events which Stryker had failed to properly report to the FDA on "MDRs" or Med Watch Reports). In response, Stryker suggested to the FDA the problem involved Calstrux and proposed to the FDA a voluntary relabeling of Calstrux to warn physicians not to mix Calstrux with any other product. During these discussions, at no time did Stryker inform the FDA that Stryker promoted the mixture of Calstrux and OP-1 to physicians; that Stryker couldn't effectively sell OP-1 without Calstrux as an extender; or that Stryker had not told surgeons and IRBs about the adverse events. Moreover, Stryker did not inform the FDA that a revised label on Calstrux was not likely to be seen by surgeons who were simply handed the mixture of OP-1 and Calstrux in the operating room and rarely, if ever, saw the Calstrux packaging; further, Stryker did not inform the FDA that surgeons were unlikely to pay attention to a letter regarding Calstrux relabeling because Calstrux was one of many bone void fillers on the market, and as such, would not be expected to attract a doctor's attention. In addition, Stryker did not inform the FDA that IRBs (which did not approve use of 510K products like Calstrux) did not know either that OP-1 was being mixed with Calstrux or that serious adverse events were associated with the use of the combination, and that, as a result, a relabeling letter on the bone void filler to the IRBs would have no significance for IRBs.

In addition, following training on the illegality of promoting the combination of OP-1 and Calstrux, the conspirators undertook efforts to conceal the ongoing conspiracy by retrieving the

written mixing instructions from hospitals and surgical staff to avoid getting caught by members of the competitor's sales force who might turn them in to the FDA, although little else changed in the way the two products were promoted. Further, the conspirators concealed the ongoing conspiracy by making a false statement to the FDA in the 2007 Annual Report about the number of units of OP-1 Putty used per patient to hide from the FDA the fact that more than 4,000 patients had been treated. A truthful disclosure that more than 4,000 patients had been treated would have alerted the FDA to a number of potential problems including that the on-label patient population may have been greater than 4,000, thus implicating a potential revocation of the HDE; and/or that there was extensive off-label use of OP-1, such as in surgeries with only one unit plus an extender, or surgeries in which there had been absolutely no clinical testing or approval of use of OP-1, all of which might invite further regulatory action. Further, in connection with an FDA audit of Stryker Biotech in the fall of 2007, Philip attempted to conceal the ongoing conspiracy by seeking to delete internal company analyses of the number of units of OP-1 used to treat patients that showed Stryker had lied to the FDA in the 2007 Annual Report; and thereafter took further steps to conceal the ongoing conspiracy by asking another employee to lie about the company's ability to determine the number of units used.

Multiple overt acts are charged, only one of which must be proved, but which include, by way of example, provision of mixing instructions, submission of false statements to the FDA, various acts to conceal the ongoing conspiracy, use of an outside surgeon/consultant to promote the mixture, and affirmative use of not sending a "dear doctor" letter to aid in achieving sales quotas.

B. Wire Fraud - Second Object of the Conspiracy (Count 1) and Counts 2 through 6

The second object of the conspiracy, wire fraud, is also substantively charged against each of the defendants in Counts 2 through 6 of the Superseding Indictment. The defendants willfully conspired and devised a scheme or artifice to defraud physicians and hospitals in order to obtain money through the deliberate manipulation of health care professionals with false, deceptive, incomplete, and misleading information into using an untested and unapproved combination of OP-1 and Calstrux.

The specific charged wirings further elucidate the nature of the fraud. In Count 2, the charged wiring is a February 14, 2006 e-mail from Whitaker to Heppner, Ard, and others arguing against sending a letter to surgeons regarding adverse events from the mixture of OP-1 and Calstrux because of an anticipated loss in sales, and noting that "many surgeons are just handed the product prior to implantation and think its [sic] all OP-1." The evidence at trial will demonstrate that these statements constitute admissions that Whitaker and his conspirators knew that information about adverse events was material to physicians and was concealed from surgeons to protect sales of OP-1; that physicians had been routinely misled by the sales force into believing that the combination device was only OP-1; and that physicians were in fact defrauded by the promotion of Calstrux as an extender for OP-1.

In Count 3, the wiring is a February 27, 2006 e-mail from Heppner to Philip, Whitaker, Ard, and others arguing against sending a letter to IRB's regarding adverse events from the mixture of OP-1 and Calstrux in part because of "serious consequences" including that IRB's will likely "[c]ease all OP-1 usage in the hospital immediately till this matter is clarified with Stryker and the

FDA. . . ." Heppner also argued that principal investigators would likely be required by IRBs to:

> . . . provide a list of all patients treated with OP-1 with charts, adverse events outcomes, etc.. This opens Pandora's Box on other users this PI [principle investigator] may not have known about, him potentially getting in trouble with the hospital as he has used OP-1 in primary fusions in a large number of cases, other off-label uses of OP-1, etc.

The evidence at trial will demonstrate that theses statements are admissions by Heppner and the conspirators that these defendants understood that information about adverse events from the mixture of Calstrux and OP-1 was material to IRBs; that the information was concealed to protect sales of OP-1; that the Stryker sales force misled IRBs and/or caused IRBs to be misled about the use of OP-1 in the hospital, whether by whom or how used (e.g. off-label surgeries, mixed with Calstrux); and that IRBs had been defrauded through the concealment of the use of the combined device of Calstrux and OP-1 which was never FDA-approved, a use which was off-label for OP-1, and a use which was expressly contrary to the Calstrux label after August 2006.

In Count 4, the charged wiring is a May 1, 2006 e-mail from Heppner to members of the sales force (copied to Ard, Whitaker and others), to notify those sales representatives that their Calstrux sales were lagging, that "issues we had in the past have been put to bed and substantial dollars are there to be made." The evidence at trial will show that these defendants knew and understood that the Stryker sales force had little success selling Calstrux except in combination with OP-1; that sales representatives who could not meet their Calstrux quotas were put on performance improvement plans; and that to meet the Calstrux quotas the sales force was required to illegally promote the unapproved combination of OP-1 and Calstrux.

In Count 5, the charged wiring is an October 23, 2006 e-mail from Ard to a sales representative enclosing mixing instructions for OP-1 and Calstrux. Ard provided these instructions

to the sales representative months after internal training that both the promotion of the combination of OP-1 and Calstrux, and the provision of mixing instructions to physicians was illegal. The evidence at trial will show that Ard provided these instructions for use in the promotion of OP-1 with Calstrux by the representative in the field.

In Count 6, the charged wiring is a January 15, 2007 e-mail from Philip to Heppner, Whitaker, Ard, and others enclosing the 2007 sales budgets. The evidence at trial will show the budget circulated by Philip required sales representatives to sell OP-1 Putty to more than 4,000 patients to meet their quotas. These sales were concealed from the FDA through the false statement in the 2007 OP-1 Putty Annual Report, and further concealed by Philip's direction to delete internal analyses that showed the average number of units used per patient was approximately 1.3, and his request to a subordinate to lie to corporate management about Stryker's ability to track the per patient usage of OP-1 Putty.

C. Misbranding Medical Devices (Counts 7 through 12)

Counts 7 through 12 charge the corporate defendant with substantive misbranding, and are also included as overt acts in the conspiracy to defraud the FDA and to commit wire fraud. Accordingly, the substantive misbranding counts constitute illegal acts for which each of the defendants is responsible because the acts were committed when each of them was a member of the conspiracy, to help advance the conspiracy, and were within the reasonably foreseeable scope of the agreement to defraud the FDA through the deliberate manipulation of physicians and others into using the unapproved and untested combination of Calstrux and OP-1. See, Pinkerton v. United States, 328 U.S. 640 (1946); United States v. Gobbi, 471 F.3d 302, 309 (1st Cir. 2006).

Each of the written mixing instructions constituted labeling for OP-1 which caused the product to be misbranded while held for sale. 21 U.S.C. §§ 331(k), 352(f); 21 C.F.R. § 801.109(b)(2),(c), and (d). The various instructions charged in Counts 7 through 12 demonstrate the widely varying techniques provided by the sales force to physicians, underscoring the inherent danger in a sales force hawking homegrown recipes not evaluated or approved by the FDA. Each of the charged instructions were provided to physicians after the internal training on March 1, 2006 that the provision of such mixing instructions was illegal, something that each of these defendants knew and understood.

D. False Statement in Annual Report (Count 13)

Finally, Count 13 charges the corporate defendant with falsely reporting to the FDA in its 2007 Annual Report on OP-1 Putty the number of units used per patient and a knowingly inaccurate estimate of the number of patients treated, namely that 6,234 units had been sold and that "[s]ince 2 units of OP-1 Putty are used per patient, it is estimated that 3,117 patients have been treated during this reporting period," when in fact, Stryker knew that less than two units were used per patient and that more than 4,000 patients had been treated during that year. The false statement to the FDA is also charged as an overt act in the conspiracy as part of the effort to conceal the ongoing illegal activity from the FDA. Thus, the substantive false statement also constitutes an illegal act for which each of the defendants is responsible because the act was committed when each of them was a member of the conspiracy, to help advance the conspiracy, and was within the reasonably foreseeable scope of their agreement to defraud the FDA.

II. Anticipated Facts

After failing to obtain a PMA for OP-1 Implant which Stryker Biotech projected would generate hundreds of millions of dollars in sales for the corporation, on October 17, 2001, Stryker Biotech obtained an approval from the FDA for OP-1 Implant under an HDE for use as "an alternative to autograft in recalcitrant long bone non-unions where use of autograft is unfeasible and alternative treatments have failed." On August 7, 2004, the FDA granted Stryker Biotech an HDE for OP-1 Putty for use as "an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion." In both HDEs, Stryker Biotech represented to the FDA that less than 4,000 individuals in the United States suffered from the condition for which the device was approved. The HDE approvals contained significant regulatory restrictions, including that no sales of OP-1 could be made to a medical facility unless the hospital's IRB had approved the use; the device could not be sold for an amount that exceeded the costs of research and development, fabrication, and distribution; and the holder of the HDE was required to file annual reports with the FDA that included the number of devices shipped or sold, and the number of patients treated. 21 U.S.C. § 360j(m); 21 C.F.R. § 814.126(b)(1)(iii).

OP-1 Putty, for use in spinal surgery, had been tested and approved by the FDA for use at two units per level of fusion, one unit on either side of the spine. It was tested and approved by the FDA to be mixed with a small amount of carboxymethylcellulose. However, the co-conspirators soon learned that OP-1 Putty could not effectively compete if sold in accordance with the FDA-approved label. Each unit of OP-1 Putty (which Stryker packaged together with a small vial of CMC) was priced at $5,250 by Stryker, which caused physicians and staff to refuse to purchase two units of OP-

1 which cost over $10,000 for a each spinal fusion, approximately twice as much as a competing bone morphogenic protein on the market. Second, physicans and staff complained to Stryker that OP-1 Putty handled poorly, was too small in volume, and that it wasn't easy to use. Accordingly, Stryker Biotech developed TCP Putty, later known as Calstrux, and applied to the FDA for approval of the product as a bone void filler under a "510K" approval, which meant it was substantially similar to other bone void fillers then on the market. Stryker never performed clinical tests in humans designed to show that Calstrux was safe when combined with OP-1; never told the FDA that it planned to market Calstrux as a "carrier" or "extender" for OP-1; and the FDA never approved Calstrux to be mixed with any other product, including OP-1.

In January 2006, Stryker held its annual national sales meeting attended by both the sales force and corporate executives. During this conference, the Vice President of Regulatory Affairs, Bernadette Alford, learned that many of the sales representatives were promoting Calstrux mixed with OP-1, and were providing recipes for the mixture to surgeons and their staff. She immediately raised the illegality of promoting the unapproved combination of Calstrux and OP-1 with Philip and Heppner. She followed up during executive meetings in Hopkinton and with a written memorandum dated February 15, 2006 regarding what she learned at the National Sales Meeting. She recommended, among other things, training the sales force to "[c]ease recommending, suggesting and preparing for use Calstrux and OP-1 . . ." and "distribute a 'dear doctor' letter advising surgeons about the adverse experiences associated with a mixture of OP-1 and Calstrux."

When the sales force learned about the planned "dear doctor" letter advising physicians and IRBs about the adverse events from the mixture of OP-1 and Calstrux, they vehemently objected. As described above, the objections from Heppner, Whitaker, and others lay bare what these

defendants knew about how physicians had been misled about what constituted OP-1, how broadly the mixture of the two products was promoted by the sales force, the widely varying home grown recipes being used by the sales force, the serious adverse events associated with the untested and unapproved mixture, and how disclosure of such facts to hospital IRB's would likely cause IRB's to stop all OP-1 usage. Once the decision was made not to send the dear doctor letter, these defendants celebrated the decision as "we dodged a bullet," "a fantastic day," and "positive information" that should be used to hit quarterly sales quotas.

Although the "dear doctor" letter was stopped, the training recommended by Alford was in fact presented on March 1, 2006 by the Vice-President of Sales, John Houghton, in a teleconference with the field sales force, including Heppner, Ard, and Whitaker. Houghton used a powerpoint slide deck during the training, a draft of which he had he shared with Philip prior to the presentation, and which powerpoint was sent to all the participants in the call. That training provided clear direction that the two products could not be promoted together, that such promotion was illegal and involved significant criminal consequences. However, other than retrieving written mixing instructions that had been left in hospitals to avoid getting caught, the evidence at trial will be that these defendants did not change the manner in which OP-1 and Calstrux was promoted in the field. To the contrary, the conspirators implemented sales budgets, quotas, and stretch goals that required the sale of the combined product in order for the field sales force to meet their quotas. Those sales representatives that failed to meet their goals were put on performance improvement plans, and if performance did not improve, were fired.

One group of witnesses who will testify at trial are members of the field sales force. In some instances these defendants personally trained individual sales representatives as well as Stryker

distributors how to present the combined OP-1 and Calstrux to physicians, and in other instances observed the training, including after the March 1, 2006 training. At National Sales Meetings where all defendants were present, Calstrux was described as the perfect "carrier" or "extender" for OP-1; and Philip was involved in discussions about how to make the mix "drier" to avoid migration and adverse events. Mixing instructions continued to be used with surgeons and surgical staff, some varying examples are set forth in the misbranding counts and in the overt acts of the conspiracy charge. After the training on March 1, 2006, and through the end of the conspiracy, the defendants were all directly involved in one or more of the following: communications with the sales force about making the mix drier, changing the sizes of Calstrux available to be combined with OP-1, actually providing mixing instructions, teaching distributors how to mix, and/or observing as distributors were taught how to mix OP-1 and Calstrux.

In addition, various executives and other employees from Stryker Biotech headquarters and its corporate parent will testify about various subjects including but not limited to the role of and vision for Stryker Biotech within the Stryker family; the regulatory process and regulatory approvals for Stryker Biotech products; the sales and budgeting process including tools such as quotas, compensation incentives, and performance improvement plans; the reporting and evaluation process for executives; constraints imposed upon sales by the unique regulatory approvals; and Philip's separation from Stryker Biotech. Among other witnesses, the government expects to call product managers, regulatory personnel, and others present at executive meetings in Stryker Biotech to describe the ongoing information received about serious adverse events associated with the mixture, the struggle to find solutions by turning to physicians consultants, the efforts to control the FDA and keep selling the combined product, and the decision not to go forward with a clinical trial on the

mixture. The headquarters witnesses will also discuss what was known to the defendants and others about the number of patients treated with OP-1 Putty, the process of compiling and submitting the Annual Report, the false statements in the Annual Report, and the efforts to conceal both the false statements and the information that made plain the falsity of those statements.

Finally, the government will call witnesses from outside Stryker Biotech including physician witnesses, some of whom acted as consultants for Stryker Biotech contemporaneously, and some of whom were subject to the misleading statements and omissions in the promotion of the product. In addition, the government may call witnesses from the FDA for various testimony including, among other matters, the nature of the approvals Stryker Biotech did and did not have, information that was and was not provided to the FDA, and the underlying rationale for the regulatory scheme. Finally, depending on the nature of defenses raised and information sought by defendants' cross examination, the government may call attorneys, both in-house and outside counsel, to rebut claims of good faith reliance on advice of counsel or a defense premised on advice of counsel.

III. Legal Issues

A. Authentication of Documentary Evidence

Prior to admitting evidence, the Court must determine "if there is a reasonable probability the evidence is what it purports to be." United States v. Luna, 649 F.3d 91, 103 (1st Cir. 2011); Fed. R. Evid. 901(a). The parties are currently in discussion about a possible stipulation regarding the authenticity of documentary evidence produced by Stryker Biotech to the government and produced by the government to the defendant from the FDA files. If appropriate stipulations are not reached, a significant number of keepers of records will be required to authenticate paper documents scanned and electronic documents produced by Stryker Biotech; the laptops of defendants Whitaker, Ard and

Heppner imaged by Stryker Biotech; the original documents from Philip's office secured and provided by Stryker Biotech; and the metadata from the electronic material that shows from where the material was obtained in Stryker Biotech electronic files. Hopefully, those keepers will not be required.

B. Hearsay Issues

1. Statements Not Offered for Truth of the Matter Asserted

Many of the out of court statements that the United States will offer, both through testimony and documents, do not implicate the hearsay rules because the relevance of the statements does not depend on the literal truth of the words.

Here, some of the out of court statements constitute "verbal acts" of the conspirators and their agents and not hearsay. "Verbal acts" include statements that "give rise to legal consequences such as the words used by contracting parties in reaching an agreement or by individuals charged with making a threat, bribe or misrepresentation." United States v. Diaz, 597 F.3d 56, 65 n. 9 (1st Cir. 2010), citing 5 Weinstein's Federal Evidence § 801.11[3] at 801-18-20. Each of the misrepresentations and material omissions to physicians, IRBs, and the FDA are not offered for the truth of the matter asserted (indeed, the statements were incomplete, untrue and/or misleading), but instead as verbal acts in furtherance of the conspiracy to defraud the FDA through the use of deceit and trickery with physicians, IRBs, and the FDA. Moreover the mixing instructions provided to physicians are not offered for the truth of the matter asserted (mixing instructions for OP-1 and Calstrux were never clinically tested or approved by the FDA), but instead are offered either as (a) written instructions which constitute the predicate for the substantive crime of misbranding in violation of the FDCA, or (b) oral statements that misled physicians about the nature of the safety,

testing, labeling and approvals of the combined product. Likewise, "bounties" offered for examples of Calstrux sold without OP-1 are verbal acts, and do not constitute hearsay.

Moreover, the United States will offer out of court statements about the association of adverse events with the mixture of OP-1 and Calstux, not for the truth of the matter asserted (whether an adverse event was actually caused or not caused by the mixture), but as evidence of motive for the co-conspirators' and their agents' actions. Non hearsay includes statements "offered to supply a motive for the listener's action." United States v. Colon-Diaz, 521 F.3d 29, 34 (1st Cir. 2008); United States v. Bailey, 270 F.3d 83, 87 (1st Cir. 2001). Here, the conspirators were exceedingly concerned that disclosure of adverse events from the mixture of OP-1 and Calstrux to physicians and IRB's would risk sales of OP-1, and even cause IRB's to cease all usage of OP-1 in their facilities. That fear caused them to take steps to conceal material information about the adverse events from physicians and IRBs. That fear caused them to "voluntarily" relabel Calstrux to warn physicians not to mix the bone void filler with other products, knowing few physicians or IRBs would see or comprehend the significance of the information, and intending to lull the FDA into taking no action regarding OP-1. That fear caused them to reach out to surgeon consultants, such as Dr. Kurz and Dr. Fishgrund, for possible "solutions" to the adverse events (*e.g.* a drier mix), or to offer smaller sizes of Calstrux (*e.g.* 5 or 10cc's instead of 15cc's), or for a contemporaneous analysis of the results of the mixture in preparation for a possible clinical trial (which resulted in unfortunate negative findings for the combined product). Reports of adverse events, including the MedWatch Reports filed by Stryker Biotech with the FDA, regardless of what conclusion was reached about whether or not the adverse event was caused by the mixture, were the motive for many of the deceitful and dishonest actions by the defendants and their conspirators and agents, and as

such, are admissible as non-hearsay.

Additionally, some out of court statements are not hearsay where they constitute directions from any conspirator to others or are part of the context to understand the events. United States v. Bailey, 270 F.3d 83, 87 (1st Cir. 2001). Thus, instructions to constitute the mix "drier" or to use smaller quantities of Calstrux in the mixture are not hearsay. Similarly, training of the sales force and distributors in how to sell the combined product is not hearsay.

Even if a statement contains elements of both hearsay and nonhearsay, the Court may admit the statement if it is relevant, and if the probative value of its intended not hearsay use is not substantially outweighed by the risk of the jury considering it for the truth of the matter asserted. United States v. Colon-Diaz, 521 F.3d 29, 33 (1st Cir. 2008).

2. Admissions of a Party Opponent.

Many of the statements that the United States intends to introduce are also admissible as admissions of a party opponent under Fed. R. Evid. 801(d)(2)(A), because they are the party's own statement in either an individual or representative capacity under Fed. R. Evid. 801(d)(2)(A), statements by a party's agent concerning a matter within the scope of the employment during the existence of the relationship under Fed. R. Evid. 801(d)(2)(D), and/or statements by a co-conspirator, during and in furtherance of the conspiracy admissible under Fed. R. Evid. 801(d)(2)(E).

Under Fed. R. Evid. 801(d)(2)(A), a party's own statement in either an individual or a representative capacity is not hearsay if offered against the party. Statements made by individual defendants will be offered against them under Fed. R. Evid. 801(d)(2)(A), including both oral and written statements (including handwritten notes). Similarly, statements made by the employees of Stryker Biotech, acting in their representative capacity as employees of the corporation, will be

offered against Stryker Biotech. Additionally, admission of statements necessary to understand the context of a defendant's statements are admissible against that defendant under this rule. United States v. Santiago, 566 F.3d 65, 69 (1st Cir. 2009).

Under Fed. R. Evid. 801(d)(2)(D) statements by a party's agent or servant concerning a matter within the scope of the agency or employment, made during the existence of the relationship, are not hearsay if offered against a party. Here, the United States must show by a preponderance that: (1) an agency relationship (such as employment) existed between Stryker Biotech and the declarant; (2) that the statements were made during employment; and (3) that the statements relate to, or concern, matters within the scope of declarant's employment. Gomez v. Rivera Rodriguez, 344 F.3d 103, 166 (1st Cir. 2003); Larch v. Mansfield Mun. Elec. Dept., 272 F.3d 63, 72-73 (1st Cir. 2001). Statements "concerning" a matter within the scope need not actually *be* within the scope; they need only be *related* to a matter within the scope. Larch, 272 F.3d at 72 (while threatening "to make life miserable" for Electric Department not within scope of employment, declarant's statements related to his oversight of said department); Woodman v. Haemonetics Corp., 51 F.3d 1087, 1093-94 (1st Cir. 1995) (in age discrimination action, supervisor's statement "[t]hese damn people– they want younger people here" deemed admissible despite having no authority to terminate employment).

In this case, the Stryker Biotech sales representatives' statements made to physicians concerning, for example, mixing OP-1 and Calstrux, concern matters within the scope of their employment, which was to sell OP-1 and Calstrux. It is not pertinent that the corporation did not direct the sales force to make the statements, or even that it directed them not to make such statements through training. All that matters is that the statements concerned matters within the

scope of the sales representatives' employment. Id. at 1094 ("Rule 801(d)(2(D) does not contemplate... that the statement be shown to have been made by the employee at the instance of her employer"). Here, Stryker Biotech gained financially when its employees made sales through the promotion of a mixture. See United States v. Cincotta, 689 F.2d 238, 241-242 (1st Cir. 1982) (unlike officers' receipt of a personal bribe, criminal liability for corporation exists where employees performed acts of the kind authorized to perform "motivated - at least in part - by an intent to benefit the corporation.").

Similarly, statements are admissible against the individual defendants if the declarant was within an agency relationship with the individual defendant. For example, statements of sales representatives who reported to Heppner, Ard, and Whitaker, or executives who reported to Philip, that are related to matters within the scope of their agency relationship would be admissible against that individual defendant. United States v. Agne, 214 F.3d 47, 54-55 (1st Cir. 2000).

3. Statements of co-conspirators

In addition, under Fed. R. Evid. 801(d)(2)(E), co-conspirator statements are not hearsay, and may be admitted for the truth of the matter asserted so long as four elements are satisfied by a preponderance of the evidence: a conspiracy existed, the defendant against whom the statement is offered was a member of the conspiracy, the declarant was a member of the conspiracy, and the declarant's statement was made in furtherance of the conspiracy. United States v. Colon-Diaz, 521 U.S. 29, 35 (1st Cir. 2008); United States v. Tom, 330 F.3d 83, 93 (1st Cir. 2003). A statement is in furtherance of the conspiracy if it "tends to advance the objects of the conspiracy as opposed to thwarting its purpose." United States v. Rodriguez, 525 F.3d 85, 101 (1st Cir. 2008).

The government anticipates offering statements from each of these defendants against each other as co-conspirators, as well as statements from other unindicted co-conspirators who have been identified by the government to the defendants as follows: Don Allard, Justin Demming, Ryan Denney, Shane Doyle, Henry Elloso, Matthew Haggarty, Patricia Hanko, Carder Higinbotham, Ken Lippe, Sheila Lopez, Darnell Martin, Stacey Mayes, Kevin Miller, Marci Miranda, Peter Murphy, Holly Pisarello, Christopher Ring, Mike Sample, Stephanie Sneed, Sean Waklee, Peter Buffo, Steve Eastwood, and Huston Ellis.

4. Hearsay Exceptions

The United States also anticipates offering various documentary evidence through one or more of the hearsay exceptions in Fed. R. Evid. 803. By way of example only, many of the e-mails, powerpoint presentations, monthly reports, sales presentations, budgets, strategic plans, minutes of meetings, and other memoranda authored by various individuals who are not defendants or conspirators, all of which are business records under Fed. R. Evid. 803(6) (as well as party admissions of Stryker). See, United States v. Munoz-Franco, 487 F.3d 25, 38 (1st Cir. 2007). As another example, under Fed. R. Evid. 803(8)(B), records, reports, statements or data compilations in any form, of public offices or agencies setting forth matters observed pursuant to duty imposed by law as to which matters there was a duty to report, fall within the exception to the hearsay rule. The FDA's Form 483 Report (Exhibit 383) which records "matters observed pursuant to duty imposed by law as to which matters there was a duty to report" is admissible under this rule. See, Fujisawa Pharmaceutical Co, Ltd. v. Kapoor, 1999 WL 543166, at 2 (N.D. Ill. 1999)(Form 483 report admitted as a public record). Similarly, the MDR's filed by Stryker Biotech (Exhibit 84.001 - 84.058) should be admissible under this rule because the reports were regularly kept by the FDA of

matters observed pursuant to duty imposed by law as to which there was a duty to report. The purpose of these records was to alert the FDA to possible safety issues involving medical devices, and the reports were entirely unrelated to proving some fact at trial. See Melendez-Diaz v. Massachusetts, __ U.S. __, 129 S.Ct. 2527, 2539-40 (2009) (documents "created for the administration of an entity's affairs and not for the purpose of establishing or proving some fact at trial . . . are not testimonial").

Respectfully submitted,

CARMEN M. ORTIZ
United States Attorney

By /s/Susan Winkler
Jeremy M. Sternberg
Susan G. Winkler
Gregory F. Noonan
Assistant U.S. Attorneys

Date: December 19, 2011

Certificate of Service

I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on December 12, 2011.

/s/ *Susan G. Winkler*
Susan G. Winkler